Effect of a telemonitoring-facilitated collaboration between general practitioner and heart failure clinic on mortality and rehospitalization rates in severe heart failure: the TEMA-HF 1 (Telemonitoring in the Management of Heart Failure) study

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study evaluated close collaboration between general practitioners and heart failure specialists, with remote monitoring, to improve the outcomes and costs for patients with coronary heart failure. The authors concluded that their intervention significantly reduced mortality and tended to reduce hospitalisations, but larger trials were required. The study was generally well reported, with appropriate methods, but the trial lacked blinding, and used envelope randomisation, which risked bias. The authors discussed the external validity of their study and reached appropriate conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study evaluated whether a close collaboration between general practitioners (GPs) and heart failure specialists, facilitated by modern remote monitoring equipment, could improve outcomes and costs for patients with coronary heart failure.

Interventions
The interventions were usual care or a complex remote monitoring (telemonitoring) intervention. All patients and close relatives received a one-hour standard education programme, from a heart failure nurse, before discharge. All patients were followed up at the out-patient heart failure clinic two weeks after discharge.

Telemonitoring patients had planned heart failure clinic follow-ups at three and six months. They were taught to use an electronic body weight scale, a blood pressure measuring device, and a cell phone, and instructed to measure their body weight, blood pressure and heart rate daily at a fixed time. Alerts were generated by the telemonitoring device, if the patients did not take their measurements, or if the measurements indicated that the patient's condition required a visit to the GP. Monitoring data was automatically transmitted to the care team. GPs were responsible for overseeing treatment changes, and had online access to heart failure specialists and the ability to contact patients outside of automated alerts from the telemonitoring device. GPs and heart failure specialists were responsible for updating medications in an online database.

Location/setting
Belgium/out-patient care.

Methods
Analytical approach:
The economic evaluation was based on a multicentre 160-patient sealed-envelope block-randomised controlled trial. Patients were recruited between April 2008 and June 2010, and follow-up was six months. The authors did not state the study perspective.

Effectiveness data:
Effectiveness data were from the trial. The sample size was determined before the trial, assuming an alpha value of 0.05, a power of 80%, an effect size of 30%, and 20% drop-out. For telemonitoring, four patients dropped out due to
lack of motivation. The nature of the intervention meant that patients and physicians could not be blinded, but data collection and analysis were conducted by people who were not involved in administering treatment. The primary outcome was all-cause mortality. Differences in all-cause mortality were measured using aggregate data and Kaplan-Meier curves. Other outcomes were the days lost due to death, hospitalisation, or dialysis; and the number of hospitalisations. The days lost by death and dialysis were calculated assuming a full 180 days of follow-up without the event. Medication changes were compared between the two groups. For telemonitoring, the frequency and nature of alerts were recorded.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The measures of benefit were all-cause mortality; days lost due to death, hospitalisation, or dialysis; and the number of hospitalisations.

Cost data:
The cost of hospitalisation was collected from billing data from the hospital in which the trial was conducted. Out-patient costs were excluded. The currency was Euros (EUR).

Analysis of uncertainty:
Statistical significance of the results was assessed using Χ² for categorical variables, or one-way analysis of variance for continuous variables, with a significance threshold of 0.05. Standard deviations were reported for most variables.

Results
At six months follow-up, there was a statistically significant difference in all-cause mortality, favouring telemonitoring (p=0.012). With telemonitoring, five patients died, and with usual care, 14 patients died. Heart failure-related hospitalisations favoured telemonitoring, but not quite significantly (p=0.056). There was no statistically significant difference between interventions, in all-cause hospitalisations. With telemonitoring, there was a statistically significant increase in medication changes, compared with usual care (p<0.01).

The total hospitalisation cost for heart failure or renal failure, was almost double with usual care (EUR 1,458), versus with telemonitoring (EUR 902), but the difference was not statistically significant (p=0.23).

Authors' conclusions
The authors concluded that their telemonitoring intervention significantly reduced mortality and tended to reduce hospitalisations for chronic heart failure, but the study was small and larger trials were required.

CRD commentary
Interventions:
The telemonitoring intervention was thoroughly described, but the content of the usual care was unclear. This might or might not be similar in Belgium to elsewhere, so the generalisability of usual care may be limited.

Effectiveness/benefits:
The effectiveness data were clearly reported, with clear rationales given for their selection. The methods of data collection and comparison seem to have been appropriate. As the authors acknowledged, the sample was small, which limited the strength of the findings. The study used block envelope randomisation, which could introduce bias, and it was unclear if the assessors, who were not involved in treatment, were blind to patient allocation, which could introduce bias. None of the outcome measures assessed patient preferences, so they might have under- or over-estimated the potential benefits of the monitoring.

Costs:
Only hospital costs were reported. The cost of the intervention, GP follow-up, medications, and other potentially relevant costs, were omitted. The cost data were reported as totals, for heart failure, renal failure, and total hospitalisation. The individual cost items, resources and prices, would have allowed an understanding of the costs of patient management, and increased the generalisability of the results. The price year was not stated, but the costs were
presumably from the two years of the trial (2008 to 2010). There was large variation in the costs, but they seemed to indicate that hospitalisation costs for telemonitoring were lower than for usual care. A probabilistic sensitivity analysis could have assessed the likelihood of this finding.

**Analysis and results:**
The results were clearly reported with appropriate variance statistics, and appropriate comparison methods for finding statistically significant differences between categorical and continuous variables. The authors thoroughly discussed their findings compared with those of other studies of telemonitoring for chronic heart failure, and gave appropriate explanations for differences in the results. They convincingly argued that their study had a different intervention to other studies, as the monitoring was daily and automatic, with more risk indicators monitored, and more direct interaction between the monitored patients and monitoring physicians. Uncertainty was assessed in a limited way, with probabilities. A thorough probabilistic analysis could have given a better indication of the underlying uncertainty in the results.

**Concluding remarks:**
The study was generally well reported, and used appropriate methods, but the reporting of the costing methods was lacking. The trial was not blind, and used envelope randomisation, which risked bias. The authors thoroughly discussed the external validity of their results and reached appropriate conclusions.

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